

ONLINE & SELF-PACED ISO 13485:2016 FOUNDATION

COURSE OVERVIEW

Our CQI & IRCA Certified Online & Self-Paced ISO 13485:2016 In-Depth Foundation Course is ideal for anyone that wants to gain a comprehensive understanding of the requirements of ISO 13485:2016 and wants to flexibility to learn at their own pace and in their own time.

Course Format: **Online & Self-Paced**

Certification: **CQI & IRCA (No. 2327)**

Duration: **8 hours**

Course Fee: **€395 per person**

Fee Includes: **Course Access for 90 Days
Phone & Email Support**



COURSE CONTENT

Module 0 - Introduction

Module 1 - Introduction to ISO 13485

- Purpose, Benefits & Structure of ISO 13485:2016
- Key Terms & Definitions
- Principles of Quality Management
- Relationship with ISO 9001
- Key Revisions of ISO 13485
- Key Concepts including PDCA, Process Approach & Risk Management

Module 2 - Establishing a QMS

- QMS Processes
- QMS Documentation
- Document Control
- Record Control

Module 3 - Management Responsibility

- Role of Top Management (Commitment, Customer Focus, Quality Policy, Quality Objectives & Change Control)
- Responsibility
- Authority and Communication
- Management Review

Module 4 - Resource Management

- Resource Planning
- Human Resources
- Infrastructure
- Work Environment & Contamination Control

Module 5 - Product Realization Part 1

- Planning of Product Realization & ISO 14971
- Customer related Processes
- Design & Development

Module 6 - Product Realization Part 1

- Purchasing
- Production & Service Provision
- Control of Monitoring & Measuring Equipment

Module 7 - Measurement, Analysis and Improvement

- Monitoring & Measurement (Feedback, Complaint Handling, Regulatory Reporting & Internal Audit, Process and Product Monitoring & Measuring)
- Control of Non-Conforming Product
- Analysis of Data
- Improvement (CAPA)

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ASSESSMENT METHODOLOGY

To complete the course successfully, each Learner must achieve an overall score of at least 70% in the final assessment which will be available after all modules are completed.

Each learner is limited to a maximum of 3 attempts.

STANDARDS NEEDED

- **ISO 13485:2016** Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes (Required & **not** included with the course)



CERTIFICATE OF COMPLETION

Successful completion of this course will entitle each Learner to receive a CQI & IRCA Recognised Certificate of Completion.

TECHNOLOGY REQUIREMENTS*



This course may be accessed by desktop, tablet, or mobile device. Please ensure a minimum internet connection of at least 1 megabit per second (Mb/s).

For the best learning experience, we **strongly recommend** Google Chrome (the latest version where possible).

**A complete and up-to-date list of technology requirements is available on our website.*

DO YOU HAVE A QUESTION FOR US?

If you have a question, get in touch with our team today!

Email: training@complyguru.ie

Phone: (061) 529100

MEET OUR MANAGEMENT TEAM & IN-HOUSE EXPERTS



EOIN PHILIP KELLY FOUNDER & CEO

Eoin founded Comply Guru & executively manages the day-to-day running of the company. He previously spent 12.5 years as a Director, President & Chief Operations Officer in a leading consulting & training provider, including over 6 years based in Chicago, USA.

He believes that there is a major gap in the world for a Learning Partner that can offer access to a growing library of industry-leading online & blended (online, classroom or virtual classroom) learning solutions that specifically focus on Quality, Regulatory Affairs & Compliance (ISO & Related Standards).



BREDA KEARNEY QUALITY DIRECTOR

Breda leads the design of Comply Guru's internationally accredited CQI and IRCA & Exemplar Global Certified Online & Blended Training Programs.

She is a highly qualified Microbiologist with over 12 years' experience in Quality, Life Sciences & the Food Safety Industry.

Breda has both designed & delivered training to hundreds of Learners in various areas across ISO 9001, ISO 13485, ISO/FSSC 22000 & ISO/IEC 17025 – at Foundation, Internal Auditor & Lead Auditor level.

She is also an accomplished Consultant & Auditor who has helped a range of small, medium & large organizations in Ireland & the U.S. design, implement and improve their Management Systems.

MEET OUR PARTNERS & INSTRUCTORS



JOHN COLLINS

John has over 20 years' experience as a Quality Professional & is a specialist in Quality Management Systems.

He has worked with all sizes and forms of organizations across a broad range of industries, including extensive experience in the Life Sciences Industry.

John has trained hundreds of Learners across Foundation-level, Internal Auditor-level and Lead Auditor-level courses in both ISO 9001:2015 & ISO 13485:2016 over the past 11 years in Ireland & abroad.



SHANE CURRAN

Shane is a specialist in Management Systems & has been working with international ISO standards and a myriad of management systems for almost 20 years.

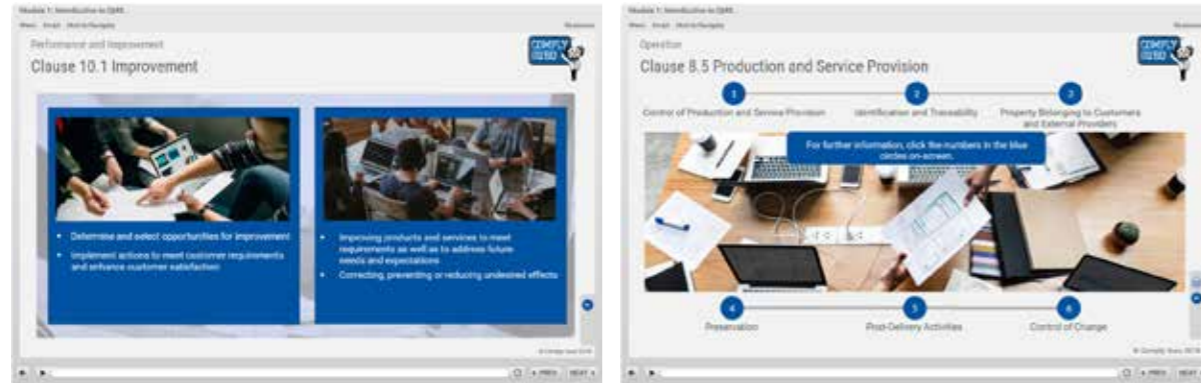
He previously worked with Antaris/SQT, who are a well-established Training Provider in Ireland, and in that time, Shane played a key role in the development & delivery of CQI & IRCA Training Courses.

Shane has trained hundreds across all areas of Management Systems in disciplines including ISO 9001, ISO 14001, ISO 45001 & ISO 13485 and brings his vast experience and skill as a Master Facilitator of Learning.

HOW YOU WILL LEARN WITH COMPLY GURU™'S ONLINE MODULES

1. HIGHLY ENGAGING, VISUAL LEARNING

All of our courses have leading edge instructional & graphic design to offer a learning content that is highly engaging and visual for an effective learning experience



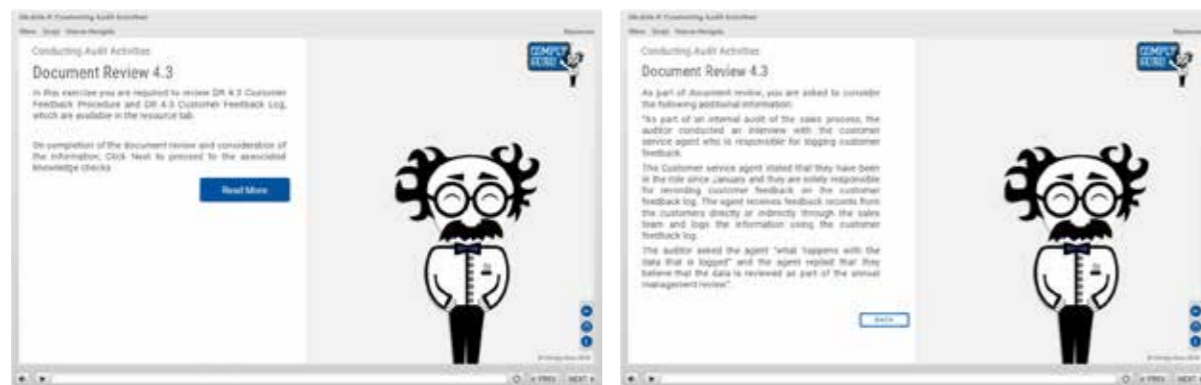
2. REGULAR INTERACTIVE KNOWLEDGE CHECKS

Throughout each Module, we have regular interactive knowledge checks to ensure that each Learner is absorbing the content as they progress through their chosen course



3. REAL LIFE SCENARIOS AND PRACTICAL EXAMPLES

An important part of learning is to ensure we provide real life scenarios and practical examples so Learners understand how the content relates to the real world.



4. EXPERT VIDEOS

Each course includes professional videos where our Subject Matter Experts will explain key concepts & topics to help each Learner master the learning content.



5. Excellent Customer Support

Should any Learner need support during their training, our team will be willing & available to assist by phone or email or within the Learning Management System, by clicking the mail icon while taking one of our courses. Just get in touch!



(061) 529100



E. training@complyguru.ie



Through the LMS

